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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,635	05/18/2000	OLIVIER BALLEVRE	P00.0164	7617

29157 7590 10/14/2004

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EXAMINER	
LUKTON, DAVID	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 10/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/508,635	BALLEVRE ET AL.	
	Examiner	Art Unit	
	David Lukton	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30,32-35 and 37-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *30,32-35 and 37-41* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Pursuant to the directives of the amendment filed 7/22/04, claims 30, 35, 37, 38 have been amended. Claims 30, 32-35 and 37-41 are now pending.

The claimed invention is now substantially different from what it was previously. Up to this point, the claimed invention was that of "promoting recovery" of an organ. Now the claimed invention is that of "increasing the protein concentration and/or rate of protein synthesis". Given the substantial change in invention, and given also the fact that the claimed invention lacks novelty, requirement of further species elections at this point is fully justified. Applicants' previous election of the small intestine as the "specific organ" (response filed 9/25/02) remains in force.

Applicants are required under 35 U.S.C. §121 to elect disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

- The first "specie" is that of one of the following:

  (a) a method of increasing the protein concentration in the small intestine; or
  (b) a method increasing the rate of protein synthesis in the small intestine

  If, for example, applicants were to elect a method of increasing the protein concentration, this would not preclude a claim which required both the concentration and the rate of synthesis to be increased. What is required is an election of either one of these as a minimal requirement for the claimed invention.

- The second "specie" is that of the degree of hydrolysis of the "milk protein hydrolyzate"(percentage of amino nitrogen relative to total nitrogen).

- The third "specie" is that of a requirement for, or absence of requirement for a carbohydrate, and if required, the identity of that carbohydrate (e.g., glucose, page 6, line 25).

- The fourth "specie" is that of a requirement for, or absence of requirement for a "fat source", and if required, the identity of that fat source (page 6, line 15+)

- The fifth "specie" is that of a specific objective of the "therapeutic efficacy" that ostensibly will be achieved by increasing protein synthesis (or concentration) in the small intestine.

As indicated above, the claimed invention lacks novelty. The claims encompass the possibility that the mammal in question is being deprived of any and all amino acid sources. As applicants may recognize, milk protein and whey protein hydrolyzates are known in the art. These have been asserted (in the prior art) to be useful for administering to neonates to provide the amino acid requirements of the growing mammal. As applicants may be aware, if (e.g.,) a newborn rat is fed just the bare minimum quantity of amino acids to sustain life, growth of all of the organs will be substantially less over time than a rat which is fed an optimal level of amino acids. As is known to the physiologist of ordinary skill, protein synthesis accompanies cell division. Accordingly, if milk protein hydrolyzates constitute the sole amino acid source in a neonate, whatever growth in the various tissues occurs must be accompanied by synthesis of protein. The physiologist of ordinary skill would recognize that, at least for a neonate, protein synthesis and tissue growth will be far greater in the presence of an amino

acid source than in the absence of such. Further, it is known in the art that for adults who have been deprived of food for one reason or another, and are exhibiting a negative nitrogen balance, providing an amino acid source will increase net protein synthesis. Further, the claims do not actually require that there be any net change in protein synthesis, i.e., the claims encompass the possibility that catabolism and anabolism are both increased, with no effect on the weight of any particular tissue. Thus, there are several embodiments within the claimed invention that are obvious over the prior art; absent further limitations, the claimed invention lacks novelty. Applicants might attempt to introduce novelty into the claimed invention by introducing a specific degree of hydrolysis of the "milk protein hydrolyzate", or by requiring the presence of specific lipids or sugars. Given the number of pertinent references that would have to be cited in order to reject all embodiments that are encompassed by the claims, an "undue burden" would be sustained by the examiner in the absence of the foregoing species elections.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are witten in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103 of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached at 571-272-0925. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

DAVID LUKTON
PATENT EXAMINER
GROUP 1600